

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 16, 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Efficacy Review and Label Review for "Permacide Brand (Ristex)
Germicidal Disinfectant Solution"
EPA Reg. No. 8383-3. Case No. 012866

DP Barcode: D250927

From: Bruce H. Mann *BH Mann*
Efficacy and Science Support Branch
Efficacy Evaluation Team
Antimicrobial Division (7510C)

To: Adam Heyward, PM 34/Portia Jenkins
Regulatory Management Branch II
Antimicrobial Division (7510C)

Thru: John W. Newland, Ph.D., J.D., Team Leader *John W Newland*
Efficacy Evaluation Team
Efficacy and Science Support Branch
Antimicrobial Division (7510C)

Michele E. Wingfield, Chief *Michele E Wingfield*
Efficacy and Science Support Branch
Antimicrobial Division (7510C)

Applicant: Sporidicin International
5901 Montrose Road
Rockville, Maryland 20852

Formulation From Label

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Phenol	1.56
Sodium Phenate.....	0.06
<u>Inert Ingredient(s)</u>	98.38
Total	100.00

(1)

LABELING:

The following comments are applicable for the proposed label pinpunched and dated 10-02-98. See attached.

1. On the back left panel, 2nd paragraph, last sentence, revise the wordings "Reduces the hazards of cross-contamination on hard surfaces" to read "Reduces the hazards of cross-contamination on hard, nonporous surfaces". ✓
2. On the back left panel, 5th paragraph, revise the phrase "...and *Polio type 1 viruses*..." to read "...and *Polio type 1 viruses* on hard nonporous, inanimate surfaces...". In the same paragraph, and after the words "...and *Mycobacterium tuberculosis* in ten minutes..." add "... at 20°C ...".
3. On the back left panel, 5th paragraph, and following the contact time "...in three minutes..." add "... on hard nonporous surfaces..."..
4. On the back left panel, 5th paragraph, and following the contact time of "...in one minute..." add "...on hard, nonporous, surfaces...".
5. A label clarification should be provided as to what species of *Herpes simplex virus* is the causative agent of the eye condition "...ocular...". We need to know the exact nomenclature as listed or indicated in the "ATCC Catalogue".

BACKGROUND:

The subject product "Sporicidin Brand (Ristex) Germicidal Disinfectant" is registered as a disinfectant for use in hospitals, medical offices, nursing homes, schools, trains, boats, restaurants, autos, health spas and toilets. Also, the product's labeling contains claims which are reported to be fungicidal, tuberculocidal, virucidal, and bactericidal. For other additional uses, refer to the product last accepted label dated 06-05-95.

The current submission is an amendment to revise the product's 10 minute exposure time to an exposure time of 3 minutes for the below listed microorganisms. This proposed decrease in exposure time is proposed for the following microorganisms: *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442), and *Trichophyton mentagrophytes* (ATCC 9533).

The present submission contains microbiological efficacy data (mrid #446778-01) and a proposed label in support of the decreased exposure time. All data reports and proposed labeling are reviewed and summarized below.

RECOMMENDATIONS:

EFFICACY SUPPORTED by the SUBMITTED DATA:

The submitted microbiological data developed by the AOAC Germicidal Spray Tests Method are adequate and supportive of the product effectiveness as a spray disinfectant (ready-to-use solution) in the presence of a moderate amount of soil (5% horse serum) for hard, nonporous, inanimate surfaces when thoroughly wetted by the spray and allowed to remain wet for an exposure time of 3 minute.

Effectiveness was demonstrated against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). Refer to attachment #1.

The submitted fungicidal data are supportive of the product as a fungicide against pathogenic fungi (*Trichophyton mentagrophytes*) for hard, nonporous, inanimate surfaces when thoroughly wetted by the spray disinfectant (ready-to-use solution) and allowed to remain wet for an exposure time of at least 3 minutes.

Effectiveness was demonstrated against *Trichophyton mentagrophytes* (ATCC 9533). Refer to attachment #1.

PRESOAK DISINFECT

HOSPITAL DISINFECTION



An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT: Acts effectively on germ laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on hard surfaces.

ACTIVE DEODORIZER: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- Kills Athlete's Foot fungus on bathroom, shower and pool surfaces
- Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes surfaces against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporcidin products.

PASSES AIAAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION including *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli*, ***Herpes simplex* types 1 and 2 (oral, ocular, and genital), *Influenza A₂* (Japan 305/57 Asian strain), *Vaccinia*, *Canine parvovirus*, *Cytomegalovirus*, *Coronavirus* and *Polio* type 1 viruses, *Trichophyton mentagrophytes* (Athlete's Foot fungus), *Mycobacterium tuberculosis* and *HIV-1* (AIDS virus) on hard surfaces.

Sporcidin
INTERNATIONAL
Rockville, MD 20852

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN Instruments and other surfaces with Sporcidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporcidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporcidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, pre-cleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

6352

change to read

Kills vegetative organisms including *Streptococcus pyogenes*, *Streptococcus salivarius*, *Escherichia coli*, ***Herpes simplex* types 1 and 2 (oral, ocular and genital), *Influenza A₂* (Japan 305/57 Asian strain), *Vaccinia*, *Canine parvovirus*, *Cytomegalovirus*, *Coronavirus* and *Polio* type 1 viruses, and *Mycobacterium tuberculosis* in ten minutes.

Kills *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Trichophyton mentagrophytes* (Athlete's Foot fungus) in three minutes.

Kills HIV-1 (AIDS virus) in one minute.

← previously accepted - see attached "Bulletin"

⊗ = location of required changes

4

Bulletin - NO CHANGE

Sporicidin

BULLETIN NOS.
303 and 403

**SPECIAL INSTRUCTIONS
FOR
CLEANING AND
DECONTAMINATION OF
SURFACES/OBJECTS
SOILED WITH
BLOOD/BODY FLUIDS
AGAINST
HIV-1 (AIDS VIRUS)**

SPORICIDIN BULLETIN NO. 303:

**Sporicidin Brand
Disinfectant Solution and Towlette
(EPA Reg. Nos. 8383-3 and 8383-7)**

- Personal Protection:**
Persons handling items soiled with blood or body fluids likely to be contaminated with HIV-1 (AIDS virus) must protect themselves by use of disposable latex gloves, gowns, masks and eye covering.
- Decontamination of Contaminated Objects:**
Immediately after use, items contaminated with blood, body fluids, or other soils that may contain HIV-1 (AIDS virus) must be thoroughly wetted with Sporicidin brand disinfectant solution or towlette for at least 1 minute before further processing.
- Cleaning Procedure:**
Following decontamination, objects and surfaces are moved to the cleaning and preparation areas where they are washed; rinsed and rough dried to remove all blood and body fluids before application of the disinfectant.
- Contact Time for Disinfection:**
Thoroughly wet entire object or surface with solution or towlette. HIV-1 (AIDS virus) is killed within 1 minute contact time. *Note: Use a 10 minute contact time for other organisms. This product should not be used for disinfection of critical or semi-critical items.
- Disposal of Infectious Materials:**
Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

SPORICIDIN BULLETIN NO. 403:

**Sporicidin Brand
Disinfectant Spray
(EPA Reg. No. 8383-4)**

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Immediately after use, items contaminated with blood, body fluids, or other soils that may contain HIV-1 (AIDS virus) must be sprayed to thoroughly wet with disinfectant for 1 minute before further processing.
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FRONT LABEL - NO CHANGE



PRESOAK AND DISINFECTANT

- BACTERICIDAL
- VIRUCIDAL**
- FUNGICIDAL
- TUBERCULOCIDAL

Active Ingredients

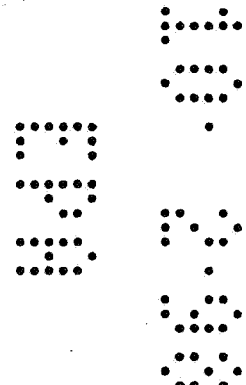
Phenol	1.56%	EPA Reg. No. 8383-3
Sodium Phenate	0.06%	EPA Est. No. 034346-NB-001
Inert Ingredients	98.38%	Net Contents: 1 U.S. Gal. (3.79 ltr.)

Keep Out of Reach of Children

CAUTION

See additional precautions on back panel

AVAILABLE IN 22 OZ. SIZE



5

Bulletin - NO CHANGE

Sporicidin

BULLETIN NOS.
303 and 403

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- Cleaning Procedure:**
Following decontamination, objects and surfaces are moved to the cleaning and preparation areas where they are washed; rinsed and rough dried to remove all blood and body fluids before application of the disinfectant.
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6

Bulletin - NO CHANGE

Sporicidin

BULLETIN NOS.
303 and 403

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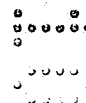
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8

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HOSPITAL DISINFECTION



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ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

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Sporcidin
INTERNATIONAL

Rockville, MD 20852

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN instruments and other surfaces with Sporcidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporcidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporcidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

6352

Change to read

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← Previously accepted -
See attached "Bulletin"

Back Label

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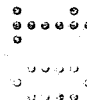
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6352

Sporcidin
INTERNATIONAL
Rockville, MD 20852



PRESOAK DISINFECT

HOSPITAL DISINFECTION



An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT: Acts effectively on germ laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on hard surfaces.

ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months in the presence of adequate moisture, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- Kills Athlete's Foot fungus on bathroom, shower and pool surfaces
- Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes surfaces against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporcidin products.

PASSES AUA² EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION

- Kills vegetative organisms including *Streptococcus pyogenes*, *Streptococcus salivarius*, *Escherichia coli*, ***Herpes simplex* types 1 and 2 (oral and genital), *Influenza A₂* (Japan 305/57 Asian strain), *Vaccinia*, *Canine parvovirus*, *Cytomegalovirus*, *Coronavirus* and Polio type 1 viruses, and *Mycobacterium tuberculosis* in ten minutes.
- Kills *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Trichophyton mentagrophytes* (Athlete's Foot fungus) in three minutes.
- Kills HIV-1 (AIDS virus) in one minute.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

PRECLEAN instruments and other surfaces with Sporcidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporcidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporcidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, pre-cleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

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TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporcidin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard, non-porous, precleaned duct surfaces. Rinse surfaces after application.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water. If necessary, consult a physician.

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